
*Now is the Time to Strengthen
Protection of Substance Use Records
by Revisiting the
Substance Use Privacy Law*

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Introduction

42 CFR Part 2 (commonly referred to as "Part 2") is the federal regulation governing the confidentiality of drug and alcohol treatment and prevention records. The regulations set requirements limiting the use and disclosure of patients' substance use medical records from certain substance use treatment programs. The Part 2 regulations were originally authorized by the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972.¹ These laws were consolidated in 1992 by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act (PL 102-321). Based on these laws, Part 2 sets out protections against unauthorized disclosure of substance use records as a way to encourage people to seek treatment. The regulations were established to assure people with substance use problems that their information would not be shared without their very specific consent, other than under several circumscribed conditions detailed in the regulations.²

After more than 40 years, it is time to revisit federal substance use privacy law and regulations to see if the solutions of the past are still relevant. Since 1972, huge changes have taken place in the organization and financing of substance use treatment. Medical treatments of substance use disorders are now more effective and widely practiced throughout the health care system. Patient centered medical homes that integrate medical and behavioral care are widely adopted. Paper medical records have been largely replaced by electronic health records (EHRs). The use and exchange of health information, especially electronic health information, is governed by a comprehensive set of federal stringent privacy and security regulations that did not exist when the substance use record protections were enacted. The Part 2 regulations were appropriate for a different time. The regulations now hinder safe, effective, high quality substance use treatment.

The Part 2 provisions that now create obstacles to safe, quality care for people who have substance use disorders were developed for an earlier time, and are not required by the law. Bringing substance use privacy protections into harmony with the Health Insurance Portability and Accountability Act (HIPAA), the Affordable Care Act (ACA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, privacy protections can be largely accomplished through regulatory changes without modifying in any way the existing substance use privacy law, 42 USC 290dd-2. However, to achieve an optimal outcome, changes to 42 USC 290dd-2 should be made. The proposed changes in this paper are designed to balance the need to facilitate communications in support of safe, high quality health care with the need to protect the privacy interests of persons who seek treatment for substance use disorders.

Changes to the Organization and Financing of Substance Use Treatment

In the 1970s and for years afterwards, substance use treatment was typically provided in small government-funded facilities largely separate from other medical care services. Health insurance rarely covered substance use treatment. That is rapidly changing. The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) dramatically expanded access to substance use treatment for millions of Americans.³ Two years later, in 2010, the ACA extended access to health insurance and expanded Medicaid for large numbers of low income and working people who did not previously have health insurance.⁴ Substance use treatment is one of the essential benefits that the ACA requires all health plans cover. The ACA extended parity coverage for substance use treatment to individual and small group health insurance and to Medicaid managed care. Medicare Part B outpatient coverage for substance use treatment also reached parity in 2014.⁵ As a result of these laws, millions of people who gained health insurance or Medicaid coverage for the first time, or whose health insurance previously had not adequately covered substance use treatment, now have the ability to pay for substance use treatment through their health insurance. The same insurers that pay for flu shots, mammograms, and appendectomies are paying for office-based opioid treatment and substance use counseling. The separate financing of medical and substance use treatment in separate treatment facilities that existed in the 1970s no longer predominates.

Changes in the Effectiveness of Substance Use Treatments

The effectiveness of substance use treatment has improved since the 1970s when mutual support groups like Alcoholics Anonymous (AA) and counseling were about the only treatments available. These services were primarily practiced in specialized addiction treatment programs, often delivered by people with lived experience of addiction but little formal medical training. AA and similar lay-led anonymous support groups held in church basements and union halls helped many recover from addiction. Although these groups continue to have value, rigorous research demonstrates that substance use disorders can be treated effectively like other medical conditions by trained medical professionals.⁶ Food and Drug Administration (FDA) approved medications for alcohol and opioid dependence are available. Well-tested treatments such as cognitive behavioral therapy and motivational enhancement therapy can reduce substance use-related health, social, and work problems. Interventions to reduce harmful consequences of substance use are effective and widely practiced in medical settings. Health care professionals in primary care and hospitals; in specialty OB/GYN, HIV/AIDS, and behavioral health programs; and in workplace wellness, Employee Assistance Programs, and military health clinics can and do provide these substance use treatments routinely. Although specialty substance use programs continue to treat many people, the

primary focus of care for addiction has clearly shifted towards medical systems that treat patients' other medical issues. Addiction specialists consult with patients' primary care providers and treat difficult and complex cases, as do their specialist counterparts in oncology, cardiology, or gynecology. The separate medical and substance use treatment silos that existed in 1972 are merging.

Substance Use Is Embedded in Medical and Mental Health

There is overwhelming evidence now that patients' substance use cannot be treated in isolation from their other physical and mental health conditions. In the 1970s, this was not widely known and treatment for addiction was largely separate from treatment of other illnesses. Since then, researchers have shown that people with substance use disorders die as much as 20 years younger than their peers from cancer, cardiovascular disorders, HIV/AIDS and STDs, injuries, and a host of other illnesses.⁷ More than 100,000 people in the United States die annually of alcohol or drug related causes, making it the fourth leading cause of preventable death, according to the Centers for Disease Control and Prevention (CDC).⁸ Alcohol and drug related illnesses and injuries cause one in ten deaths of working age adults.⁹ Depression, bipolar disorder, post-traumatic stress, nicotine dependence, and sleep disorders commonly co-occur with alcohol and drug use.¹⁰ Medically ill inpatients who also have alcohol or drug disorders are at greatly increased risk of rapid rehospitalization after discharge and greater health care use and costs.¹¹ Patients who have medical illnesses such as diabetes or cardiovascular disorders and who also have a substance use disorder use health care services two to three times more often than their peers with just diabetes or heart problems, and cost of care is similarly much higher.¹² Untreated, alcohol or drug use during pregnancy dramatically increases risk of poor birth outcomes, neonatal intensive care use and greater infant and maternal health care use. But treated as part of prenatal care, birth outcomes, infant and maternal health use and costs are no different from their non-substance using peers.¹³ Screening and brief alcohol counseling of traumatically injured patients not only reduces subsequent substance use, but also cuts the likelihood of re-injury and rehospitalization in half.¹⁴ Treating patients' substance use in isolation from their medical and mental conditions, which predominated care in the 1970s, is not the standard of good medical practice today.

Changes in Collection, Exchange, and Regulation of Health Information

Health care records have rapidly moved from paper to electronic documentation. Part 2 was created to protect the paper records in certain substance use treatment programs from disclosure without patients' explicit consent. Paper records were stored at program sites and physically secured in locked cabinets. Records could only be shared by photocopy and mail. The present state of health information storage and exchange is much different. Widespread adoption of EHRs has been greatly stimulated by requirements by Medicare and other insurers that health care providers submit bills electronically. The HIPAA of 1996¹⁵, and HIPAA privacy regulations¹⁶ promulgated in 2000 accelerated this shift. Further impelling adoption of EHRs was the 2009 passage of the HITECH Act¹⁷ which provided billions of dollars to incentivize health professionals and health settings to adopt EHRs and created the threat of financial penalties if providers do not meaningfully use EHRs.

Electronic health information exchanges (HIEs) improve quality of care, safety, care coordination and reduce risks of medical errors.¹⁸ The power of "big data" analytics to analyze EHRs from many physically separate providers is creating opportunities for improving care, reducing costs, and better managing episodes of care. Regulations implementing HIPAA, the HITECH Act, and similar federal legislation have created consistent privacy and security standards for the exchange of health information for the purpose of treatment, administration and payment, and protections against disclosure of health information without patient consent. Blocking certain substance use providers from accessing health records from these exchanges, which the Part 2 regulations do, isolates patients in these programs from these powerful exchanges of health information and from the protections of HIPAA and HITECH regulations governing these exchanges.¹⁹

For many patients with substance use disorders, who are screened and treated for their addictions by health care providers outside the specialty substance use programs governed by Part 2, their health information is shared (and protected) within the general health exchanges governed by HIPAA and HITECH regulations. In the 1970s, medical records were paper charts. Part 2 regulations, now more than 40 years old and governing separate substance use paper medical records, are out of step with the health care's rapid adoption of EHRs; its capacity to quickly exchange information; the federal privacy and security regulation covering these EHRs and exchanges; and the increasing treatment of patients' substance use in health care systems not covered by Part 2 but covered by HIPAA.

Retaining or Changing Part 2

There are understandable reasons that the substance use confidentiality law and regulations remain in force. But over the last 45 years, compelling reasons have grown for protecting substance use medical information with the stronger protections now afforded other sensitive health information. Remarkably, the law on which Part 2 is based²⁰ makes harmonization with HIPAA and HITECH privacy protections very possible. Many of the components of the Part 2 regulation that make safe and coordinated care most difficult could be updated through regulatory changes to be consistent with HIPAA and HITECH protections without any change in the underlying law. In the concluding section of this paper, we identify several specific ways that the law could be further strengthened to promote safe, high quality care while at the same time protecting patients with substance use disorders from prejudicial or discriminatory use of their health information.

Retaining Part 2 as it is may appear attractive. The first principle of medicine is “do no harm.” If changes to the substance use confidentiality regulations might increase the possibility of harms to patients, the default might be to keep Part 2 the way it is now. Knowing that sensitive information about alcohol or drug use would be protected could encourage people with substance use disorders to seek treatment. Substance use records are protected by Part 2 from disclosure and use in criminal investigations and proceedings except under conditions defined in the regulation. But then again, so are the health records covered by HIPAA and HITECH. Part 2 does have more stringent due process and court order provisions.²¹ Patients can control and limit who has access to their substance use information. If consent is granted, it is for a specific purpose, to a named provider and expires on a certain date. Patients can choose whether to disclose their substance use history or treatment to their health care providers. This control may protect them from prejudicial care by health care providers who might be influenced by patients' substance use history.²² Research has shown that the more that individuals with substance use disorders fear discrimination and negative attitudes, the more likely they are to be secretive about their substance use, conceal negative and distressing personal information, and stop treatment prematurely.²³ But less than one person in seven who has a substance use disorder ever receives treatment, even with the current Part 2 protections in place.²⁴ With Part 2 contributing to the separation of substance use treatment from the rest of medicine, most patients are never asked about their substance use and never get treated.

However, there are significant down sides to retaining Part 2 as it is. Separating substance use treatment information from patients' other medical information risks unsafe, uncoordinated and uninformed care. Dangerous drug-drug interactions frequently occur between prescribed medications such as sedatives, anesthetics or opioids, the medications used to treat substance use disorders, and the alcohol or illicit substances patients may be using. If substance use programs are prevented from sharing information about patients' substance use and medications prescribed to treat their substance use with primary care or

emergency care providers, the risks of accidental death from overdose or fatal drug-drug interactions can be grave.²⁵ Fatal interactions between prescribed medications and patients' alcohol and/or other drug use increased tenfold in a decade, according to a recent study published in JAMA.²⁶

The Part 2 requirement of explicit patient consent creates numerous problems. Care coordination and hand-offs from one treatment setting to another become very difficult or impossible. Unlike referrals elsewhere in medicine, physicians are unlikely to know whether a patient referred for substance use care actually gets there. Unless a patient gives specific consent, a substance use treatment program cannot tell a referring physician anything. Separation of substance use from the rest of medicine creates three problems: primary care lacks the capability to coordinate patients' medical and substance use treatment; substance use treatment programs lack the capability to coordinate patients' medical and substance use care; and patients are put at risk of unsafe, uncoordinated and uninformed care. Part 2 permits health care providers to "break the glass" to access patients' substance use information without consent in bona fide emergencies. However, emergency providers generally have no way of knowing if substance use information is hidden by Part 2 restrictions.

Technological solutions to segmenting permission, tracking disclosure to specifically named provider and restricting redisclosure and terminating consent at a date specified as required by Part 2 do not exist in the integrated information sharing of health insurance exchanges. The practical effect is summarized in a 2015 commentary in the *New England Journal of Medicine*: "These regulations [42 CFR Part 2 rules], which are overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA), already frustrate accountable care organizations and health information exchanges, since their elaborate consent requirements make it difficult or impossible to share patient data related to substance-use disorders. As a result, many organizations exclude such information from their systems, undercutting efforts to improve care and efficiency."²⁷

The benefits of mining "big data" for comparative effectiveness research or for targeting interventions based on predictive analytics of health claims are being denied patients with substance use disorders by recent SAMHSA and CMS interpretations of Part 2. In late 2013, the Centers for Medicare and Medicaid Services (CMS) began scrubbing from research data sets any Medicare or Medicaid claim with a substance use disorder diagnosis or related substance use treatment code. This action by CMS affects about 4.5% of inpatient Medicare claims and about 8% of inpatient Medicaid claims from key research files,²⁸ impeding a wide range of research aimed at improving care for patients with substance use disorders. Studies of conditions disproportionately affecting patients with substance use disorders such as HIV/AIDS, hepatitis C or depression are also hampered by these cuts.

Compounding the problems with the Part 2 regulation is that it is unenforceable. Part 2 lacks a statutory basis for the penalties for unauthorized disclosure. Section 42 CFR § 2. 4. states that “Under 42 U. S. C. 290ee-3(f) and 42 U. S. C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.” These two laws were specifically amended in the 1992 ADAMHA Reorganization Act and recodified at 42 U. S. C. 290dd-2.²⁹ The Part 2 regulation was never updated and still refers to the penalties in the 1970 and 1972 laws. But, more tellingly, ADAMHA Reorganization Act at 290dd-2(f) section on penalties now states “Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18.” There is no section of Title 18, the US Criminal Code, which corresponds to privacy violations, medical records or substance use confidentiality. **There is no legal basis for the Part 2 penalties.** By contrast, violators of HIPAA privacy regulations are subject to hefty fines, revocation of professional and facility license or certification, and patients may sue violators for unauthorized disclosure under state laws.³⁰

The table below summarizes the benefits and the challenge of moving toward a HIPAA standard of privacy for substance use records.

Benefits of Moving towards a HIPAA Standard	Challenges in Moving towards HIPAA
Promotes patient centered medical homes that treat the whole person, not artificially segmenting out substance use. Increases likelihood of safer treatment because providers have access to all relevant patient information. Patients less likely to be exposed to drug-drug interactions. Substance use providers can access patients’ medical information, and primary care or emergency care and access patients’ substance use information.	May expose patients to prejudicial treatment by health care providers who have negative stereotypes about substance using patients.
Encourages substance use screening and care management by primary care, and appropriate consultation or referral to specialty care for more complex and difficult cases. More patients with substance use conditions will get treated.	
Enables efficient referral and hand off between levels of substance use care and feedback between medical and substance use providers.	Patient would lose some control over the information that providers and other non-health care providers see.
Facilitates participation of substance use treatment system in health information exchanges, giving patients’ health care provider access to important information such as medications and prior treatments.	Exposes substance use treatment information to non-treating health providers, increasing possibilities that sensitive information is disclosed without authorization.
Encourages use of existing software for EHRs and for health information exchange and uniformly applying the privacy and security regulations that are already employed in health systems rather than technologically complex and unproven data segmentation for substance use data.	May result in increased costs for substance use treatment programs to upgrade EHR software.
Incorporates substance use information into the routine EHR fields to better identify patient needs, track interventions, and manage complex medical conditions.	

Benefits of Moving towards a HIPAA Standard	Challenges in Moving towards HIPAA
Promotes participation of specialty substance use providers in HIEs and ACOs to produce better patient outcomes.	May create competition because current specialty substance use treatment providers will no longer be operating in separate silos.
Requires comprehensive delineation of patient rights in the HIPAA notice of privacy practices so patients better understand the rules regarding disclosure of information, patient rights to access, amendment, accounting of disclosures and restrictions on use.	
Simplifies billing and promotes payment efficiency by health plans.	Removes the Part 2 requirement for written authorization for payment.
Embraces stronger and enforceable HIPAA penalties for unauthorized disclosures and uses in contrast to much smaller and unenforceable Part 2 penalties.	

Going Back to the Law

The law on which Part 2 is based, 42 USC 290dd-2, is simple. Part 2 is complex. Most, but not all, barriers described earlier to safe, high quality and confidential patient care result from Part 2 regulation, not the law. HHS could eliminate most barriers by returning to the law, and redrafting regulations to fit with the privacy protections of HIPAA and HITECH.

The law applies to records “maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States.”³¹ **All records are covered**, not only those in specific substance use treatment programs that “hold themselves out”³² as providing substance use services, as set out in Part 2 regulations. The law applies to substance use screening and brief intervention in hospital emergency departments, to pharmacotherapy and medical management by primary care physicians, to treatment of co-occurring substance use and mental health disorders in behavioral health programs and in psychiatrists’ offices, and to health claims and payment records of health insurers. All of the protections of the law, especially the protection against unauthorized access to records by law enforcement, extend to all substance use records, regardless of the program or entity generating them. The law does not single out for coverage separate and distinct substance use facilities that hold themselves out as providing substance use services. Nor does the law shield from its protections substance use records generated by other medical service providers. Virtually every health care provider and health insurance plan is a “program or activity” “directly or indirectly assisted” by the Federal government, and falls under the law.

The 1992 law explicitly permits access to patient records without prior patient authorization by “qualified personnel for the purpose of conducting **scientific research**, management audits, financial audits or program evaluation” and prohibits disclosure of patient identities.³³ Part 2 permits disclosure for research purposes “if the program director makes a determination” that the researcher is qualified, patient information will be protected and the research design has been reviewed.³⁴ Part 2 defines a program

director as “the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.”³⁵ In 2015, CMS eliminated all information about substance use diagnosis or substance use treatment from Medicare and Medicaid research data sets after determining that Part 2 required the explicit approval of Part 2 covered specialty substance use program directors for data to be made available to qualified researchers.³⁶ CMS could not determine if a substance use record in the Medicaid and Medicare research data set came from a Part 2 covered program, so it eliminated all substance use data. Though consistent with Part 2, the decision is at odds with the law. The 1992 law extends privacy protection to all substance use records, including administrative claims submitted by thousands of health care providers to Medicaid and Medicare. The CMS Administrator or her designee has the authority under the law (but not the regulation) to approve research access to the Medicare and Medicaid research administrative data. The Part 2 regulations are not consistent with the law.

Part 2 is very prescriptive about the **content of patient consent**. The regulations specify that written consent must include the specific name of individuals authorized to receive the records, purpose of authorization and date the authorization will expire.³⁷ The law, however, simply states that disclosure is permitted in accordance with the “prior written consent of the patient.”³⁸ The consent requirements in Part 2, which create huge problems in a modern environment of EHRs, HIEs and patient centered medical homes, are not mandated by the law. Regulators could adopt HIPAA and HITECH regulatory standards which describe the process that covered entities must use to obtain individuals’ written authorization for any use or disclosure of protected health information.³⁹

The 1992 law is silent about disclosures of PHI without patient authorization for the purposes of **treatment, payment, and health care operations activities**. It authorizes HHS to prescribe regulations to define disclosure. Regulators could adopt the HIPAA regulations which detail the conditions under which PHI may be disclosed without prior patient authorization to carry out treatment, payment, or health care operations.⁴⁰

“**Qualified Service Organizations (QSOs)**”⁴¹ are nowhere referenced in the 1992 law. The Part 2 QSO definition, codified in the 1980s, describes the privacy protection responsibilities of an individual or entity which “provides services to a [Part 2 covered substance use treatment] program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy and has entered into a written agreement with a program.”⁴² HIPAA Business Associate regulations, developed decades later, describe the conditions under which a covered entity may engage a business associate to help it carry out its health care activities and functions.⁴³ The covered entity must have a written business associate contract that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with the HIPAA Rules’ requirements to protect the privacy and security of PHI.⁴⁴ Adopting the HIPAA Business Associate regulations to cover the obligations of individuals or entities that provide services to covered entities would greatly simplify Part 2, and would be consistent with the 1992 law.

These modifications could all be accomplished by HHS through regulatory processes without any changes in the law, while retaining the laws strong protections from unauthorized disclosure. But fundamental problems remain with the unenforceability the law and absence of certain protections against

discriminatory use of substance use records. The next section describes specific amendments to 290dd-2 that would modernize and strengthen the substance use privacy law.

Bringing Substance use Privacy Protections into Alignment with 21st Century Healthcare Privacy Protections

This section identifies specific modifications to the law governing substance use records, 42 USC 290dd-2, to fit current conditions and remedy problems that the Part 2 regulations have created in delivering safe, effective health care for people who have substance use disorders. The Part 2 regulations are so out of date that the first two pages of the regulations quote verbatim as their legislative authority the 1970 and 1972 alcohol and drug abuse privacy laws that were explicitly omitted by the 1992 ADAMHA Reorganization Act and amended and recodified in a new section 42 U. S. C. 290dd-2.⁴⁵ Although recodified, the new law failed to include enforceable penalties by referencing non-existent provisions in Title 18 of the Federal criminal code. Thus, to legitimately protect the confidentiality of drug and alcohol treatment information, 42 U. S. C. 290dd-2 needs to be updated to be consistent with the stronger and more enforceable HIPAA penalties.

The suggested statutory modifications are called “*The Confidentiality and Addiction Patient Protection Act of 2015 (CAPPA)*.” The modifications suggested reinforce Congress’s longstanding concern that individuals not be made more vulnerable as a result of seeking treatment for a substance use disorder.

Likewise, privacy must be appropriately balanced against the need for better coordinated and integrated care. The nation’s health delivery system has dramatically changed since the privacy laws were passed in the early 1970s. The healthcare ecosystem will continue to be shaped by the ACA, HITECH and parity laws. These laws emphasize the importance of substance use treatment as part of comprehensive health care and place behavioral health care services on par with treatment for other medical illnesses. Federal law promotes the coordination of all health services delivered by multiple providers to improve outcomes and improve population health.

There are several places where revisions and remedies could be made to address the shortcomings of the substance use privacy law. A specific line-by-line commentary describes the rationale for each proposed modification to 42 U. S. C. 290dd-2. Following that is the suggested updated 42 U. S. C. 290dd-2 and the specific strike-outs and additions to modernize and harmonize the law, CAPPA.

1. Lines 2-8 address the applicability of the protections. Previously, the protections were limited to “programs”. We believe the protections should extend to any substance use disorder information no matter in which setting the treatment is rendered. Therefore, as long as the treatment, rehabilitation, or research is rendered by an entity that is conducted, regulated, or assisted by any department of the United

States, the confidentiality protections apply. Further, the statute appeared overly broad to protect participants of prevention, training, or education programs so those provisions were struck.

2. Lines 10-15 address permitted disclosures when the patient provides written authorization. Rather than allowing the Secretary to prescribe separate requirements for the written authorization, CAPPa requires harmonization with the HIPAA authorization requirements. To the extent providers and plans use common forms for authorization, efficiencies will result, and cost savings can be achieved. Further, common elements in an authorization form will facilitate consistent programming for EHRs and promote health information exchange. Initial consent to disclose health information, consistent with HIPAA, may include disclosure and redisclosure of information to health information exchanges, accountable care organization, managed behavioral health organizations, payers or other integrated care entities for the purposes of treatment, payment, and health care operations without additional patient consent.

3. Lines 21-24 continue the permitted disclosure for research that existed in the 1972 statute. However, CAPPa provides additional patient protections requiring such research to comply with the human subjects' protections regulations and restricts the research reports from disclosing patient identities external to the research entity.

4. Lines 25-29 permit the disclosure of information to business associates, consistent with HIPAA. The qualified personnel language was previously intended to allow disclosures for program evaluation, audits, and other financial and management audits. This provision has been operationalized in a number of ways through Part 2 via an audit and evaluation exception as well as the qualified service organization permitted disclosure. To achieve consistency with HIPAA, and to require the more robust privacy and security requirements of business associate agreements, we revised the qualified personnel language to explicitly reference business associates. However, in addition to executing a business associate agreement, consistent with the spirit and intent of the qualified service organization requirements currently described in Part 2, CAPPa requires the business associate to resist in judicial proceedings.

5. Lines 30-32 include one of the most important revisions in CAPPa to permit sharing of information without patient consent to health care providers and health plans "involved in the patient's treatment" to facilitate integrated care, improve patient safety and better coordinate care for patients. Consistent with the treatment, payment and health care operations exceptions within HIPAA, CAPPa allows health providers and health plans to share substance use disorder information for the limited purposes of providing or coordinating health care and related services, for payment purposes and for health care operations (which would include quality reporting and other data reporting such as HEDIS). To mitigate the effect of such disclosures (and provide additional protections the current law and regulations do not currently afford), CAPPa includes explicit prohibitions on redisclosure and use of the information as well as robust non-discrimination and enforcement provisions. Under the 1992 law, except in cases of medical

emergency, a patient has a right to decide what, if any, substance use disorder treatment information is disclosed to his or her health care providers. The Part 2 regulations require the patient to specifically authorize the disclosure in the form of a written consent (as specified by 42 CFR 2.31) except in cases of medical emergency (42 CFR 2.51). This section would make the minimally necessary health care information available to appropriately diagnose and safely treat patients. Section 13405(a) of the HITECH Act requires HIPAA covered entities and business associates to honor an individual's request to restrict disclosure to a health plan if payment for services is made out of pocket. This provision would continue to apply to persons receiving substance use treatment.

6. Lines 33-38 address the care coordination entities and health information exchanges that may not clearly fall within the health care provider or health plan definitions of subsection D above. As contemplated by the ACA, patients will be receiving their health care through a variety of structures. The Part 2 requirement that a single individual or organization be named on a Part 2 consent is wholly inconsistent with the important national goal of patient centered health homes. The Part 2 requirement functions to discriminate against addiction treatment patients in two ways. First, general medical/surgical patients have the ability to provide a broader consent, but substance abuse treatment patients are restricted from doing so. Second, substance abuse treatment patients are effectively excluded from participation in HIEs due to the rigidity of the consent regulations and the technological inability to uniformly segregate substance abuse data in accordance with the stringent requirements contained in Part 2. As a result, a digital divide exists between general medical/surgical patients and substance abuse treatment patients as substance abuse treatment patients are not given an equal opportunity to participate or decide who should have access to their information. This not only perpetuates discrimination against substance abuse treatment patients (the very stigma that the SUD Confidentiality Law and Part 2 was intended to address) but it also interferes with the important objectives of the ACA. Therefore, CAPPa permits the sharing of information to integrated care arrangements provided all participants of the entity sign a participation agreement that safeguards the privacy and security of the information, restricts disclosure of information except as permitted by the statute, and requires the entity to resist in judicial proceedings for disclosure of the information.

7. Lines 46-52 align CAPPa with HIPAA by incorporating the “minimum necessary” language modeled after the HIPAA privacy rule and the HITECH Act. The Secretary is authorized to articulate in regulations additional limitations to define “minimum necessary”. Specific data elements and rules regarding “minimum necessary” may provide additional patient protections and establish clear and consistently accepted disclosure authorization requirements to further advance interoperability. As currently required by HIPAA, psychotherapy notes (which include clinical notes about substance use counseling), have greater protections and may not be released without patient authorization.

8. Lines 53-62 enhance the restrictions on the use of records in criminal, civil, and administrative proceedings to provide patients additional important protections. The relaxation of some disclosures without patient authorization must be balanced against necessary restrictions on the use of that information which patients understand is being gathered for their health care treatment. Information shared among health care providers, health plans, care coordination entities, and HIEs is intended to promote better healthcare, improved safety, and decreased costs through electronic sharing of information. Patients will be more willing to seek treatment and honestly share information with their healthcare providers if that information is used only health care treatment purposes. This information should not be used for non-health care purposes without a specific court order. The current court order requirements in 42 CFR 2.61-2.67 provide specific due process protections. These court order requirements would no longer apply to just treatment programs but any entity that received substance use disorder treatment information protected by this statute. If such information is wrongfully obtained, illegally disclosed, or used in violation of this statute, enhanced penalties and exclusion from evidence remedies now apply. Most important to patients, CAPPa expressly provides that any substance use disorder information cannot be used in any criminal, civil, or administrative proceedings without an appropriate court order, or in the case of civil or administrative proceedings with patient written authorization.

9. Lines 71-73 harmonize the many public safety and public health reporting requirements that exist under HIPAA and under most state laws. Although child abuse reporting was permitted under a subsequent amendment to the statute, other types of mandated abuse reporting technically violated the confidentiality statute. Similarly, mandated disease reporting and other public health treatments for infectious diseases required creative maneuvering around the existing statute and its regulations. CAPPa recognizes the importance of public health and public safety communications and expressly permits not only child abuse reporting, but also domestic violence, elder abuse, and mandated public health reporting to appropriate national, state, or local authorities.

10. Lines 74-75 codify an existing exemption permitted under the confidentiality regulations allowing limited disclosure to law enforcement for purposes of investigating a crime on program premises or against program personnel.

11. Lines 76-81 provide meaningful enforcement for violations of this confidentiality statute. The current law has questionable enforcement authority. United States Attorneys are responsible for prosecuting cases involving the unauthorized or improper disclosure of patient records. However, the sanctions for such violations and the fines were set forth in 42 USC 290ee-3(f) and 42 USC 290dd-3(f). The prosecutorial obligation is based on the Department's responsibility to enforce all federal criminal statutes 28 USC 516. Sections 290ee-3 and 290dd-3 were eliminated on July 10, 1992 by Public Act 102-321. Even though

290dd-2 was included as Section 543 in Public Act 102-321, there was a statutory drafting error, and the fines were eliminated and only reference Title 18. Specifically, the Penalties provision now reads, “Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18.” No mention of privacy law violation fines, penalties, or offenses exist in Title 18. Thus, the current confidentiality obligations have no enforcement authority. Entities receiving unauthorized information would likely not be subject to penalties unless a common law breach of privacy lawsuit is filed. To remedy this error and provide enhanced patient protections, CAPPa adopts the substantial HIPAA penalties contained in the HITECH Act. Additionally, CAPPa provides that any disclosures of information in violation of this statute shall be excluded from evidence and deemed inadmissible for use in any administrative, civil, or criminal proceeding.

12. Lines 89-96 include a new non-discrimination provision. CAPPa extends the extensive employment, insurance and housing non-discrimination provisions, and remedies that currently apply to genetic information to substance use disorder information. Moreover, the nondiscrimination provisions included in the ACA have also been expressly applied to persons receiving substance use treatment and to substance use information protected under this statute.

13. Lines 97-100 address preemption. Section 2.20 of the current confidentiality regulations includes a provision addressing the relationship to state law. However, CAPPa takes it to another level by expressly recognizing that greater protections or rights for a patient shall govern and supersede any other inconsistent statutory provisions. This statute was written primarily for the benefit and protection of patients, and their rights are – and should be – paramount.

Conclusion

Both real and perceived confidentiality barriers continue to block successful coordination of care efforts for patients across the nation. If the consent roadblocks are not addressed, patients with substance use disorders will continue to be deprived of their right to participate in safe, high quality and confidential health care. Providers must be able to treat a whole person in an integrated delivery system in a coordinated way to yield better outcomes. The 1992 law on which Part 2 is based, 42 USC 290dd-2, provides a strong basis for simplifying and modernizing substance use privacy regulation. Most of the outdated barriers to good and confidential substance use care result from Part 2 regulations designed for another time. HHS could return to the 1992 law, and redraft regulations that fit with the privacy protections of HIPAA and HITECH. But that would not be enough. The 1992 confidentiality statute must be reformed to afford patients greater protections against unlawful disclosure of their substance abuse treatment, limit the use of information shared for non-health care purposes, provide meaningful enforcement and penalties, and more effectively prevent discrimination.

¹ 42 USC Ch. 60: Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation program; Title 21 – Food and Drugs, Chapter 16, Drug Abuse Prevention, Treatment and Rehabilitation Act.

² US Department of Health Education and Welfare Confidentiality of alcohol and drug abuse patient records. Fed Reg. 1975 May 9;40(91):20522–20542. US Department of Health and Human Services Confidentiality of alcohol and drug abuse patient records–PHS. Final rule Fed Reg. 1987 Jun 9;52(110):21796–21814.

³ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Pub. L. 110-343, 122 Stat. 3765 (enacted Oct. 3, 2008).

⁴ Patient Protection and Affordable Care (ACA), Pub. L. 111-148, 124 Stat. 199, H.R. 3590 (enacted Mar. 23, 2010).

⁵ PL 110–275 Medicare Improvements for Patients and Providers Act of 2008. Section 102, Elimination of discriminatory copayment rates for Medicare outpatient psychiatric services. <http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf>

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¹⁵ Health Insurance Portability and Accountability Act of 1996 (HIPAA) Section 264 Pub. L. 104-191, 110 Stat. 1936 (enacted August 21, 1996); as modified by the ACA, Pub. L. 111-148.

¹⁶ HIPAA Privacy Regulations, 45 C.F.R. Parts 160 and 164.

¹⁷ Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title VI of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009).

¹⁸ <http://www.healthit.gov/providers-professionals/care-coordination-improved-through-health-information-exchange>; <http://www.healthit.gov/providers-professionals/benefits-electronic-health-records-ehrs>. Yaraghi N. (2015). An Empirical analysis of the financial benefits of health information exchange in emergency departments. *Journal of the American Medical Informatics Association*, ocv068.

¹⁹ HIPAA and HITECH protect health information from disclosure to law enforcement and legal proceedings without patient consent, except under tightly constrained conditions (45 CFR § 164.502(j)(2); 45 CFR §§ 164.512). Unauthorized access to psychotherapy notes (which include substance use notes) is restricted, like in Part 2 (45 CFR § 164.508(a)(2)). Only minimum information necessary to pay claims is received by insurance companies (45 CFR §§ 164.506(c) and 164.502(b)) and patients who privately pay may request that no information about that treatment or service be shared (45 CFR § 164.522(a)(1)). Third parties, such as employers, cannot access health information without authorization or Court order (45 CFR § 164.504(f)(2)(ii)(C)).

²⁰ 42 USC 290dd-2.

²¹ Disclosures to law enforcement under HIPAA also generally requires explicit patient authorization or a court order (www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/505.html) 45 CFR §§ 164.512(e); 45 CFR § 164.512(e). The stringent Part 2 court order provisions are contained in 42 C.F.R. 2.61-2.67.

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- ²⁸ Frakt AB, & Bagley N. (2015). Protection or Harm? Suppressing Substance-Use Data. *NEJM*.
- ²⁹ 42 USC 290dd-3 and 290ee-290ee-3, under Subtitle C, Section 131 of Pub. L. 102-321 were amended and replaced by the new 290dd-2. See 106 Stat. 366-370 (July 10, 1992).
- ³⁰ 42 U.S. Code § 1320d–5 - General penalty for failure to comply with requirements and standards.
- ³¹ 42 USC 290dd-2(a)
- ³² 42 CFR Part 2 2.11.
- ³³ 42 USC 290dd-2(b)(2)(B)
- ³⁴ 42 CFR §2.52; 52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987
- ³⁵ 42 CFR §2.11
- ³⁶ Frakt AB, & Bagley N. (2015). Protection or Harm? Suppressing Substance-Use Data. *NEJM*.
- ³⁷ 42 CFR Part 2 subpart C 2.31
- ³⁸ 42 USC 290 dd-2(b)(1)
- ³⁹ 45 C.F.R. § 164.508.
- ⁴⁰ 67 FR 53268, Aug. 14, 2002, as amended at 78 FR 5698, Jan. 25, 2013; 45 CFR § 164.506
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf>
- ⁴¹ 42 CFR Part 2 § 2.11
- ⁴² 42 CFR Part 2 Subpart B §2.11
- ⁴³ Definitions of “business associate” and “covered entity” at 45 CFR 160.103, 45 CFR 164.502(e), 164.504(e), 164.532(d) and (e)
- ⁴⁴ <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/>
- ⁴⁵ 290dd-2 was included as Section 543 in Public Act 102-321, 106 Stat. 368-370 (enacted July 10, 1992).

1 **§ 290dd–2. Confidentiality and Addiction Patient Protection Act of 2015 (“CAPPA”)**

2 **(a) Requirement**

3 Records of the identity, diagnosis, prognosis, or treatment of any patient which are
4 maintained in connection with substance use treatment, rehabilitation, or research, which
5 is conducted, regulated, or directly or indirectly assisted by any department or agency of
6 the United States shall, except as provided in subsection (e) of this section, be confidential
7 and be disclosed only for the purposes and under the circumstances expressly authorized
8 under subsection (b) of this section.

9 **(b) Permitted disclosure**

10 (1) Consent

11 The content of any record referred to in subsection (a) of this section may be disclosed in
12 accordance with the prior written authorization of the patient with respect to whom such
13 record is maintained consistent with the written authorization elements required by the
14 HIPAA privacy regulations, 45 CFR 164, authorized by and set forth in Section 264 of Public
15 Law 104-191 (42 U. S. C. 1320d-2).

16 (2) Method for disclosure

17 Whether or not the patient, with respect to whom any given record referred to in
18 subsection (a) of this section is maintained, gives written authorization, the content of such
19 record may be disclosed as follows:

20 (A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

21 (B) To individuals and entities for the purpose of conducting scientific research in
22 accordance with human subjects protections as codified in the common rule at 45 C. F. R.
23 46, HIPAA and HITECH provided such reports do not disclose patient identities to individuals
24 or entities external to the research.

25 (C) To business associates as defined in the HIPAA and Section 13400 of HITECH provided
26 such entities execute a business associate agreement and such agreement requires the
27 business associate to (1) safeguard the privacy and security of the information in
28 accordance with HITECH, and (2) resist in judicial proceedings or any efforts to obtain
29 information not permitted by this statute.

30 (D) To and among health care providers and health plans involved in the patient’s treatment
31 for purposes of providing or coordinating health care and related services, and for payment
32 and health care operations as defined by HIPAA.

33 (E) Within accountable care organizations described in 42 U. S. C. 1395jjj, health information
34 exchanges, health homes defined in 42 U. S. C. 1396w-4(h)(3) or other integrated care
35 arrangements (in existence before, on, or after the date of the enactment of this paragraph)
36 involving the interchange of electronic health records defined in 42 U. S. C. 17921(5) for the
37 purposes of attaining interoperability, improving coordination, reducing health care costs,
38 and enhancing patient safety.

39 (F) If authorized by an appropriate order of a court of competent jurisdiction granted after
40 application showing good cause therefor, including the need to avert a substantial risk of
41 death or serious bodily harm. In assessing good cause the court shall weigh the public
42 interest and the need for disclosure against the injury to the patient, to the physician-
43 patient relationship, and to the treatment services. Upon the granting of such order, the
44 court, in determining the extent to which any disclosure of all or any part of any record is
45 necessary, shall impose appropriate safeguards against unauthorized disclosure.

46 (3) Minimum necessary standard

47 Except as authorized by a court order granted under subsection (b)(2)(F) of this section, the
48 use, disclosure or request for the content of a record shall, to the extent practicable, be
49 limited to the minimum necessary to accomplish the intended purpose of such, use,
50 disclosure or request, respectively. For purposes of compliance with this provision, the
51 “minimum necessary” shall be based upon guidance issued by the Secretary in accordance
52 with section 13405 (b)(1)(B) of the American Recovery and Reinvestment Act of 2009.

53 **(c) Use of records**

54 (1) Criminal Proceedings: Except as authorized by a court order granted under subsection
55 (b)(2)(F) of this section, no record referred to in subsection (a) of this section may be used
56 to initiate or substantiate any criminal charges against a patient or to conduct any
57 investigation of a patient.

58 (2) Civil or Administrative Proceedings: Except as authorized by written authorization or a
59 court order granted under subsection (b)(2)(F) of this section, no record referred to in
60 subsection (a) of this section may be used in any civil or administrative proceedings.

61 (3) Any record disclosed or used for purposes not permitted by this statute are subject to
62 the penalties and exclusion from evidence as set forth in subsection (f) of this section.

63 **(d) Application**

64 The prohibitions of this section continue to apply to records concerning any individual who
65 has been a patient, irrespective of whether or when such individual ceases to be a patient.

66 **(e) Nonapplicability**

67 (1) The prohibitions of this section do not apply to any interchange of records within the
68 Uniformed Services or within those components of the Department of Veterans Affairs
69 furnishing health care to veterans; or (2) between such components and the Uniformed
70 Services.

71 (2) The prohibitions of this section do not apply to the reporting under State law of
72 incidents of suspected child abuse and neglect, domestic violence or elder abuse or other
73 mandated public health reporting to the appropriate State or local authorities.

74 (3) The prohibitions of this section do not apply to disclosures to law enforcement for a
75 crime on program premises or against program personnel.

76 **(f) Penalties**

77 Any person who violates any provision of this section or any regulation issued pursuant to
78 this section shall be fined in accordance with HIPAA penalties contained in the HITECH Act,
79 42 U. S. C. 1320D and any such disclosures of information or wrongful use of information in
80 violation of this statute shall be excluded from evidence and be deemed inadmissible for
81 use in any administrative, civil or criminal proceeding.

82 **(g) Regulations**

83 The Secretary shall prescribe regulations to carry out the purposes of this section. Such
84 regulations may contain such definitions, and may provide for such safeguards and
85 procedures, including procedures and criteria for the issuance and scope of orders under
86 subsection (b)(2)(F) of this section, as in the judgment of the Secretary are necessary or
87 proper to effectuate the purposes of this section, to prevent circumvention or evasion
88 thereof, or to facilitate compliance therewith.

89 **(h) Non-discrimination**

90 (A) To encourage patients to seek treatment, the non-discrimination employment,
91 insurance and housing provisions, protections and remedies in the Genetic Information
92 Nondiscrimination Act of 2008 (Public Law 110-233) 42 U. S. C. 2000ff shall extend to
93 substance use information.

94 (B) The nondiscrimination provisions and associated remedies in Sections 2706 and 1557 in
95 Public Law 111-148 shall apply to persons receiving substance use treatment and to any
96 record referred to in subsection (a) of this section.

97 **(i) Preemption**

98 To the extent of any conflict among the provisions in this statute and other federal or state
99 statutes, the provisions that provide the greater protections or rights to the patient shall
100 govern and supersede any inconsistent provisions.